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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,495	02/20/2002	Walter Herman Maria Louis Luyten	JAB-1526	3238

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EXAMINER

ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 12/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,495

Applicant(s)

LUYTEN, WALTER HERMAN
MARIA LOUIS

Examiner

Jon Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18,22-45 and 48-54 is/are pending in the application.
- 4a) Of the above claim(s) 2-18,22-45 and 48-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/20/02.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 10/4/04. The amendment has been entered. Claims 1-18, 22-45, 48-54 are currently pending in the application and are addressed herein.

Election/Restrictions

Applicant's election with traverse of Group I (claim 1) in the reply filed on 10/4/04 is acknowledged. The traversal is on the ground(s) that Groups I XIII and XXI relate to a single inventive concept under PCT rule 13.1. This is not found persuasive because Group I is a different method, with distinct method steps compared to Groups XIII and XXI. Specifically, Group I is a method wherein the cell/tissue comprises a nucleotide sequence that encodes a lethal protein, while Groups XIII and XXI encompass a method wherein a compound is administered to the cell/tissue. The method of Group I does not require the compound of Groups XIII and XXI and Groups XIII and XXI do not require the nucleic acid encoding a lethal protein. Therefore Group I is not the same inventive concept as the other Groups.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2-18, 22-45, 48-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/4/04. Claim 1 is examined herein.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 10/20/02 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

Claim 1 is objected to because it appears that Applicants have misspelled the “lethal” in line 8 of the claim. Instead of “lethal”, the claim reads “letal”. The examiner considers this to be merely a typographical error, and has examined the claim based the proper spelling “lethal” instead of “letal”. However, Applicants must correct the error in response to this action or justify the use of the word “letal”.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recited the phrase “said protein” in line 13. However claim 1 comprises a “lethal protein” (see line 2) and “a Gas1 protein” (see line 5). Without an indication as to which “protein” the phrase “said protein” refers to the claim is unclear and indefinite. Amending the claim to indicate precise which protein “said protein” refers to would obviate this rejection.

Claim 1 is also rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP

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§ 2172.01. The instant claims encompass inhibiting the function and/or expression of a Gas1 protein (see step (b)). However the method does not indicate the actual method step(s) that are used to inhibit the function/expression of the Gas1 protein. The omitted steps are: the exact method steps for inhibiting function/expression of the Gas1 polypeptides. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Written Description Guidelines for examination of patent applications indicates, “the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus.” (See MPEP 2100-164)

The instant claim encompasses “an otherwise lethal protein”, “a Gas1 protein”, “Gas1 derivative”, as well as “a protein in the signal transduction pathway of which Gas1 is a component”. However, the specification does not appear to indicate any specific “Gas1

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derivatives” or any proteins “in the signal transduction pathway of which Gas1 is a component”. Furthermore, regarding the Gas1 proteins, the only Gas1 protein disclosed in the specification is the Gas 1 protein disclosed as SEQ ID NO:2. Regarding the “otherwise lethal proteins” the only one specific protein that is an “otherwise lethal protein” is the specific protein disclosed as SEQ ID NO:4. However, the claims encompass a genus of “otherwise lethal proteins”, a genus of “Gas1 proteins/derivatives” and a genus of proteins in the Gas1 signal transduction pathway wherein each genus of molecules encompass thousands, (and possibly millions of different species molecules considering every possible molecule encompassed by the claims. For instance, the phrase “a Gas1 protein” does not limit the claim to any specific protein, therefore, the claims encompass any variant of Gas1 including all variants, fragments, “functional equivalents” and “bioprecursors thereof” (see p. 9 middle paragraph of the specification). It is noted that the variants, functional equivalents, etc. even encompass molecules that are structurally unrelated to Gas1; that is the claims encompass molecules which do not share the same structure (i.e. sequence is totally different) but yet has the same function as Gas1. It is noted the specification and prior art do not recognize any such molecules other than Gas1 (SEQ ID NO:2) itself. With respect to the “lethal proteins” it is noted that the claims encompass any protein that is lethal to the neuronal cell. However, the specification has only described one such protein (SEQ ID NO:4). Therefore, the claims encompass thousands, or maybe millions of different “lethal proteins” that have not been described including molecules that have different structures and different functions. Finally, The claim also encompasses any “protein that is in the Gas1 signal transduction pathway”. This would include any protein that is either directly or indirectly involved in Gas1 function, and includes possibly thousands of different proteins,

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including ones yet to be discovered wherein the protein could have unrelated structures and different functions. Looking to the specification for guidance as well as the prior art. It appears that no other proteins in the Gas1 (SEQ ID NO:2) signal transduction pathway have yet to be identified. Therefore, the claims clearly encompass molecules which have not been adequately described in the specification.

Additionally, claim 1 is also rejected under 35 U.S.C. 112, first paragraph (in view of the written description rejection above), as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As mentioned above, the claims encompass sequence for which there is no written description provided in the specification and for which include substitutions, fragments, etc. of disclosed sequences. Without a clear indication of the sequence encompassed by the claims one of skill in the art would not know how to make or use the claimed invention without performing an undue amount of additional experimentation.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon Eric Angell, Ph.D.
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DAVID T. NGUYEN
PRIMARY EXAMINER